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10/506,827

09/07/2004

Janusz B. Pawliszyn

PAT 804W-2

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05/30/2006

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EXAMINER

DIRAMIO, JACQUELINE A

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|---|--|
| Office Action Summary | Application No. 10/506,827 | Applicant(s) PAWLISZYN, JANUSZ B. | |
| | Examiner Jacqueline DiRamio | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-107, 109, 118 and 119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 101-107, 109, 118 and 119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2006 has been entered.

Status of the Claims

Claims 1 – 100, 108, and 110 – 117 have been cancelled. New claim 119 has been added. Currently, claims 101 – 107, 109, 118 and 119 are pending.

Withdrawn Rejections

All previous rejections of the claims have been withdrawn in light of Applicant's amendments and arguments filed March 24, 2006.

Response to Arguments

Applicant's arguments, see p6-12, filed March 24, 2006, with respect to the rejection(s) of claim(s) 101 under 35 U.S.C. 102 as being anticipated by Pawliszyn (US 5,691,206) or Fretot et al. (Solid-Phase Microextraction (SPEM): A new tool in pheromone identification in lipidoptera, *J. High Resol. Chromatogr.* 1997, 20, pp.340-342) have been fully considered and are persuasive. The amendment to claim 101

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wherein the positioning device now comprises a catheter is not taught or anticipated by either of the cited prior art references. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 101 is rejected under 35 U.S.C. 102(e) as being anticipated by Pompidou et al. (US 6,689,603).

Pompidou et al. teach a device for in situ analysis of a substrate, wherein the substrate includes an animal or animal tissue, said device comprising:

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at least one microsystem 2 (fibre) having a coated end which is at least partially coated with specific antibodies 4 (an extraction phase) for binding (extracting) an antigen (component) present in the substrate; and

a flexible rod 1 (positioning device) for guiding said coated end into position within the animal or animal tissue, said flexible rod comprising:

a deformable catheter for placement within an animal or animal tissue through which said microsystem extends, said catheter having an open end for positioning within said animal or animal tissue and said catheter being immobilized during sampling with respect to the animal or animal tissue; and

a rigid support 3 (fibre holding region) attached to said microsystem, said support being movable with respect to the catheter, to move said coated end of the microsystem into or out of the animal or animal tissue (see Figures 1, and 3-5; and column 1, lines 8-12 and lines 35-65; column 2, lines 2-56; column 3, lines 6-10 and lines 43-59; column 4, lines 4-19 and lines 49-64; column 5, lines 5-19 and lines 52-54; column 6, lines 13-17; and column 8, lines 58-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 102, 103, 106, 109 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510).

The Pompidou et al. reference, which is discussed in the 102(e) rejection above, teaches that the device is biocompatible, but fails to teach that the microsystem (fibre) is coated with a biocompatible protection layer, such as polypyrrole or derivatized cellulose. Pompidou et al. further fail to teach that the extraction phase, i.e. specific antibodies, contain a fluorescent label or enzyme, or that the microsystem (fibre) comprises a plurality of microsystems.

Gourley et al. teach a sensor device comprising an optical fiber for use in sensing the concentration of a component in a medium. The optical fiber 12 contains a sensing element 18, which comprises a coating of a polymeric matrix. The polymeric matrix, which preferably comprises dimethylsiloxane polymers, allows for permeability of the component the concentration of which is to be determined or measured by the sensor system. The fiber and sensing element further contain an overcoating 20, which preferably comprises a cellulosic material (derivatized cellulose). The sensor system is

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created in order to allow for it to be suitable for use in vivo in a human patient.

Additionally, the fiber and sensing element utilizes an optical indicator, preferably a fluorescent dye, which is sensitive to the component of interest and allows for determination of the concentration of the component. Further, the system utilizes one or more optical fibers, which allows for measuring a plurality of different components of interest (see Figure 1; and column 2, lines 60-65; column 3, lines 62-68; column 4, lines 1-60; column 6, lines 39-55; column 7, lines 34-58; and column 9, lines 5-68).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. the coating with a biocompatible layer and also the use of polymeric matrix coating as an extraction phase as taught by Gourley et al. because Gourley et al. teach the benefit of the coatings of a sensor system with a cellulosic material and a polymeric matrix coating, because they allow for permeability of the component of interest to be measured and allow for the sensor to be suitable for use in vivo in a human patient. It also would have been obvious to use a fluorescent indicator with the extraction phase as taught by Gourley et al. because the indicator is sensitive to the component of interest and allows for determination of the concentration of the component. Further, it would have been obvious to use multiple fibers as taught by Gourley et al. because multiple fibers allows for measuring a plurality of different components of interest.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Colburn et al. (US 2003/0183758).

The device of Pompidou et al. meets the structural limitations of both the fiber and extraction phase, therefore, enabling the device to be useful in a variety of analytical instruments, however, Pompidou et al. fail to teach the use of MALDI-TOFMS analysis specifically.

Colburn et al. teach that matrix-assisted laser desorption/ionization (MALDI) in combination with time-of-flight (TOF) analyzers have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers (see paragraph 0003, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the MALDI-TOFMS combination as taught by Colburn et al. as the analytical instrument for the device of Pompidou et al. because Colburn et al. teach the benefit of using MALDI-TOF analyzers because they have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Riviere et al. (US 2003/0180954).

Pompidou et al. further fail to teach the addition of a calibrant to the extraction phase of the fiber.

Riviere et al. teach the use of polydimethylsiloxane coated fibers as skin-imitating membranes in order to study permeation of chemicals into these membranes (see

paragraph 0037). The absorption parameters, referred to as molecular descriptors, of each chemical compound is obtained by comparing to its calibration standard, wherein the standards were created by analyzing fifty compounds and their subsequent molecular descriptors (see paragraphs 0167-0169). The calibration standards determine the system constants, which reflect the properties of the membrane (fibers) and will not change with different solutes, therefore, the molecular descriptors of unknown/study compounds can be obtained (see paragraph 0170).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the extraction phase of the microsystem of Pompidou et al. a calibration standard (calibrant) as taught by Riviere et al. because Riviere et al. teach the benefit of using calibration standards to determine the system constants because they reflect the properties of the fibers, which will not change and thus enable the absorbance of unknown compounds to be studied.

Claims 107 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Pawliszyn (US 5,691,206).

Pompidou et al. fail to teach that the device comprises an openable housing for said microsystem (fiber), wherein said housing can comprise a needle.

Pawliszyn teaches a device for solid phase microextraction comprising a fiber 6, which contains a coating selective for a component of interest (extraction phase), and a metal sleeve 24 and hollow needle 18, which houses the fiber. The purpose of the housing of the fiber by the metal sleeve and hollow needle is to protect the fiber from

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damage when not in use. Further, the device is enabled for solid phase microextraction in both in-vivo and in-vitro samples (see Figures 1 and 2; and column 2, lines 10-21; column 3, lines 5-16; and column 5, lines 10-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. an openable housing comprising a needle for housing the microsystem (fibre) as taught by Pawliszyn because Pawliszyn teach the benefit of housing a fiber for use in in-vitro or in-vivo sampling for extraction purposes in order to protect the fiber from damage when not in use.

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Shor et al. (US 5,424,187), particularly column 11, lines 38-45;

Jimenez et al. (US 2003/0135195); and

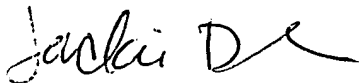
Iyer et al. (US 5,640,470).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

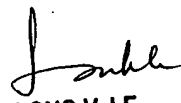
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jackie DiRamio
Patent Examiner
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